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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,412	03/20/2002	Herbert Markl	02481.1781	5276

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,412

Applicant(s)

MARKL ET AL

Examiner

David M. Naff

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/9/05 & 5/10/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-50, 52-82 and 84-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-50, 52-82 and 84-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendments of 3/9/05 and 5/10/05 amended the specification, canceled claims 51 and 83, and amended claims 52, 61, 62 and 82.

Claims examined on the merits are 39-50, 52-82 and 84-92, which
5 are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 39-50, 52-82 and 84-92 are rejected under 35 U.S.C. 103(a)
10 as being unpatentable over Portner et al (listed on form PTO-1449) for reasons in the previous office action of 10/6/04, and for reasons herein.

The claims are drawn to a method for culturing cells using a reaction system and to a reaction system for carrying out the method wherein the reactions system contains a container for dialysis fluid and a culture vessel for culturing cells and a membrane module in fluid communication with the container and vessel. The module contains two spaces separated by a dialysis membrane. Dialysis fluid is circulated through one of the two spaces and culture fluid is circulated through the other space. A first gas is introduced into the vessel for culturing cells, and a second gas is introduced into culture fluid in the membrane module. Also claimed is the membrane module alone with a gas supply means to supply gas to one of the spaces.

Portner et al disclose (Figure 2a, page 405) a reaction system as required by the present claims except for supplying gas to culture fluid in the dialysis module (membrane module). Portner et al disclose (page 404, right col, 3rd complete paragraph) that when cells are pumped through the external module, the cells can suffer from oxygen limitation. Figure 3a (page 406) discloses a reactor without an external module where a culture chamber is separated from a dialyzing chamber by a dialysis membrane. Air is supplied to the culture chamber. In Figure 3b, air is supplied to the dialyzing chamber.

It would have been obvious to supply air to space containing circulating culture liquid containing cells in the dialysis module of the reactor of Figure 2a of Portner et al to prevent cells from

suffering oxygen limitation as disclosed on page 404 since it would have been apparent from Figure 3a that oxygen can be supplied to cells in a chamber separated from a dialyzing chamber by a dialysis membrane. The conditions of dependent claims not disclosed by Portner et al are conditions that would be expected to require control when using the reaction system of Portner et al, and such conditions would have been matters of optimization depending on individual preference well within the skill of the art. Providing air to the dialyzing chamber as required by certain claims would have been suggested by Figure 3b of Portner et al.

Response to Arguments

Applicants urge that the invention involves supplying two gases to the system, i.e. a first gas to space for culturing cells and a second gas to culture fluid in a membrane module. However, Portner et al supply gas to the culture vessel (Fig 2a), and this gas can be considered a first gas. For reasons stated in the rejection, it would have been obvious to also supply gas to the dialysis module (also shown in Fig. 2a) of Portner et al to prevent cells from suffering oxygen limitation as disclosed on page 404 since it would have been apparent from Fig. 3a that oxygen can be supplied to cells in a chamber separated from a dialyzing chamber by a dialysis membrane.

Applicants assert that Portner et al does not disclose that supplying first and second gases enables large scale capacity of the present system. However, the claims encompass the same capacity as used by Portner et al. Furthermore, the oxygen limitation problem

disclosed by Portner et al would have been expected to occur when using a large scale capacity for the same reason it occurs using the capacity disclosed by Portner et al.

Conclusion

5 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date
10 of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,
15 however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be
20 reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 751-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

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DMN
7/25/05